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Prophylactic antibiotics in open mesh repair of inguinal hernia – A randomized controlled trial

V. Gomathi Shankar*, K. Srinivasan, Sarath C. Sistla, S. Jagdish

Department of Surgery, JIPMER (Jawaharlal Institute of Postgraduate Medical Education and Research), Puducherry 605006, India

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ABSTRACT

The role of prophylactic antibiotics in mesh repair of inguinal hernia is unclear. A Cochrane meta-analysis in 2005 concluded that "antibiotic prophylaxis for elective inguinal hernia repair cannot be firmly recommended or discarded" and "further studies are needed, particularly on the use for mesh repair." So, we designed a study to define the role of prophylactic antibiotics in mesh repair of inguinal hernia.

We conducted a prospective, randomized, double-blind, trial comparing wound infection rates in 450 patients (225 received intravenous Cefazolin, 225 received a placebo) undergoing primary inguinal hernia repair electively using polypropylene mesh. 334 patients who completed a followup period of one month were analyzed. Age, American Society of Anesthesiologists class, type of hernia, type of anesthesia, grade of surgeon, pre and postoperative hospital stay and duration of operation were recorded. CDC criteria was used to define wound infection.

Groups were well matched for all preoperative variables studied. The overall infection rate was 8.7% (29 out of 334). The incidence of wound infection in antibiotic group was 7% and 10.5% in control group. One from each group developed deep surgical site infection. Most of the infections occurred between the 7th and 12th post-operative day after discharge from the hospital.

Antibiotic prophylaxis was associated with decreased incidence of wound infection when compared to control group, but the difference was not statistically significant. Based on our results we do not recommend the routine use of antibiotic prophylaxis in elective mesh repair of inguinal hernias.

1. Introduction

Inguinal hernia repair is one of the most common procedures performed by general surgeons. It is estimated that 3,000,000 inguinal herniorrhaphies are performed per year in the United States, Europe and Asia.[1] Inguinal hernia repair is considered as a clean surgery, where prophylactic antibiotics do not have any role, at least in non-mesh repairs. Even though hernia is classified as a clean surgery, the reported incidence of wound infection varies from 0% to 9%.[2] As more and more surgeries are done as day care procedures, many of these infections are often recognized first in the outpatient setup, after discharge from the hospital.[3]

The role of prophylactic antibiotics in mesh repair of inguinal hernia is unclear. The first randomized control trial on the role of antibiotic prophylaxis in mesh repair of inguinal hernia was done in 2001 by Yerdel et al., who advocated the use of prophylactic antibiotics.[4] However, subsequent trials have produced varied results. A Cochrane meta analysis on this topic in 2004 concluded that antibiotic prophylaxis in mesh repair of inguinal hernias can neither be recommended nor discarded.[5] Hence, we designed this study to define the role of prophylactic antibiotics in prevention of wound infection in mesh inguinal hernia repair and to analyze the risk factors for wound infection in mesh inguinal hernia repair.

2. Patients and methods

The study was conducted in the department of general surgery, JIPMER. It was a prospective randomized controlled study.

2.1. Inclusion criteria

All consecutive patients with primary unilateral or bilateral uncomplicated inguinal hernia who underwent mesh repair during a period of twenty months from November 2006 to June 2008 in the department of general surgery in our institute were included in our study. Out of the 571 patients who underwent meshplasty during the study period, 121 patients were excluded as per the exclusion criteria given below:

* Corresponding author. Tel.: +91 9751062569.
E-mail address: drgomathishankar@gmail.com (V.G. Shankar).

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1. Recurrent hernia
2. Immuno suppressive disease (HIV, Malignancy) or medication
3. Diabetes mellitus

2.2. Surgery and post operative management

After informed consent, 450 patients were randomized into antibiotic group and control group by sealed envelope method on the day before the surgery. Patients in the antibiotic group received injection Cefazolin 1 g intravenously at the time of induction of anesthesia. Normal saline was used as the placebo in the control group.

Ioprep was the antiseptic used for skin preparation in all patients. Groin shaving was done the day before surgery. All patients underwent a standard tension free mesh repair using a polypropylene mesh. A standard sterile dressing was applied post operatively. No post operative antibiotics were used. Dressings were removed at 48 h after surgery, when the first wound inspection was done. No further dressings were applied. Patients were discharged at the discretion of the operating surgeon.

2.3. Followup

Wounds were inspected daily during the hospital stay and the next followup visit was scheduled 7–10 days later when the patients came for suture removal.

All patients were educated about the symptoms and signs of SSI and were instructed to report to us in case they developed any such symptoms and signs. The next wound inspection was scheduled on the 30th post operative day. Followup was done by residents who where blinded to the drug used. SSI was defined as per the CDC (Center for Disease Control) criteria.

2.4. Parameters studied

The parameters studied included the following:

1) Patient related factors like demographic data, ASA score (determined by anesthesiologists preoperatively), preoperative hospital stay, type of hernia and co morbid illnesses if any.
2) Surgery related factors like type of anesthesia, antiseptic used for skin preparation, grade of surgeon, duration of surgery.
3) Incidence of surgical site infection.

The study was concluded in June 2008, by then, out of 450 patients who had entered the study, 334 patients had completed one month followup.

2.5. Statistical analysis

Statistical analysis was done using SPSS statistical software. The association between SSI and antibiotic status were analyzed using chi square test. The effect of duration of surgery, hospital stay by unpaired t-test and the grade of surgeon, ASA grade were analyzed with Mann Whitney test.

3. Observations

Among the 334 patients with one month followup, 172 were in the antibiotic group and 162 were in the control group. Demographic data were comparable between the two groups. Mean age of the patients was 45, with range from 15 to 83 years. Majority of the patients had unilateral hernia, while there were 27 bilateral hernias including both the groups. Most of the patients did not have any associated co morbid illness (Table 1).

Table 1
Baseline characteristics.

	Antibiotic group *n* (%)	Control group *n* (%)	Total *n* (%)	*p* Value
Age[a] (in years)	44.44 ± 15.59	45.56 ± 16.43	44.99 ± 15.99	0.523
Sex[b]				
Male	171 (99.4%)	159 (98.1%)	330 (98.8%)	0.358
Female	1 (0.6%)	3 (1.9%)	4 (1.2%)	
ASA grade[b]				
ASA I	157 (91.3%)	151 (93.2%)	308 (92.2%)	0.511
ASA II	15 (8.7%)	11 (6.8%)	26 (7.8%)	
Co morbidity[b]				
Present	24 (14%)	11 (6.8%)	35 (10.5%)	0.050
Absent	148 (86%)	151 (93.2%)	299 (89.5%)	
Type of hernia[b]				
Unilateral	151 (87.8%)	156 (96.3%)	307 (91.9%)	0.005
Bilateral	21 (12.2%)	6 (3.7%)	27 (8.1%)	

[a] Values expressed in mean ± standard deviation.
[b] Values expressed in numbers and percentage.

Surgery related factors like type of anesthesia, grade of surgeon and duration of surgery were analyzed and were comparable in the two groups. The mean duration of surgery was 53 minutes and was comparable in the study groups. The mean pre-operative hospital stay, mean post operative stay as well as the total hospital stay was comparable in both the groups (Table 2).

29 patients (8.7%) out of the total of 334 patients developed wound infection, out of which 12 patients belonged to the antibiotic group and 17 patients belonged to the control group. There was no statistically significant difference in the incidence of wound infection between the study groups, even though the number of infected patients was less in the antibiotic group ($p = 0.344$) (Table 3).

SSI was grouped as follows (using CDC criteria):

Superficial SSI: Wound cellulitis/erythema/purulent discharge from the wound
Deep SSI: Mesh infection.

No significant difference was found between the study groups on analyzing the sub types of infection.

Age, gender, ASA grade, co morbid illness, uni/bilateral hernia did not have any significant correlation with SSI rates (Table 4).The grade of the surgeon did not have any statistically significant

Table 2
Operative data.

	Antibiotic group	Control group	Total	*p* Value
Preoperative stay (in days)[a]	4.38 ± 3.11	3.93 ± 3.00	4.16 ± 3.06	0.178
Anesthesia[b]				
SA	153 (89%)	142 (87.7%)	295 (88.3%)	0.695
GA	5 (2.9%)	7(4.3%)	12 (3.6%)	
LA	13 (7.6%)	13(8.0%)	26 (7.8%)	
Epidural	1 (0.6%)		1 (0.3%)	
Grade of surgeon[b]				
Consultant	25 (14.5%)	13 (8.1%)	38 (11.4%)	0.084
Resident	147 (85.5%)	149 (92%)	296 (88.6%)	
Duration of[a] surgery (in minutes)	53.54 ± 15.82	52.60 ± 15.28	53.06 ± 15.56	0.582

[a] Values expressed in mean ± standard deviation.
[b] Values expressed in numbers and percentage.

Table 3
Surgical site infection.

Infection	Antibiotic group *n* (%)	Control group *n* (%)	Total *n* (%)	*p* Value
Present	12 (7%)	17 (10.5%)	29 (8.7%)	0.344
Absent	160 (93%)	145 (89.5%)	305 (91.3%)	0.344
Cellulitis	7 (4.1%)	5 (3.1%)	12 (3.6%)	0.128
Mesh infection	1 (0.6%)	1 (0.6%)	2 (0.6%)	0.128
Pus discharge	4 (2.3%)	11 (6.8%)	15 (4.5%)	0.128

bearing on the incidence of SSI ($p = 0.669$). The mean duration of surgery was 58.45 minutes in the group of infected patients when compared to 52.52 minutes in patients without infection, which was of borderline statistical significance ($p = 0.05$) (Table 5). Patients with wound infection had a significantly longer preoperative hospital stay ($p = 0.035$). The post operative stay was similar in both groups. However, the total hospital stay was significantly longer in patients with wound infection ($p = 0.001$) (Table 6).

4. Discussion

The incidence of surgical site infection following mesh repair of inguinal hernia has been ranging from 0% to 9%.[3] Such a wide range on SSI rates is due to the fact that studies differed in various aspects like difference in study design (retrospective, non-randomized vs. prospective, randomized), surveillance methods (surgical team vs. independent observer), definition of wound infection (no definition vs. CDC definitions), duration of follow-up, type of operation (mesh repair vs. non-mesh repair).[6] In our study, the overall infection rate was 8.7%, in patients undergoing elective mesh repair of primary inguinal hernias. The incidence of wound infection was 10.5% in the control group and 7.0% in the antibiotic group. Even though the incidence of wound infection was higher in the control group, it was not statistically significant ($p = 0.344$).

The power of the trial ($\alpha - 0.05$, $\beta - 80\%$,) was based on the assumption that antibiotic prophylaxis will reduce the wound infection rate from 8% (SSI Rates in our institute)[7] to 1.7%(the SSI rate in the largest RCT in this subject).[8] The sample size calculated was 348 patients. We expected a dropout of 20%, since the dropout rate was higher than expected we continued the study till we had 450 patients.

The incidence of wound infection (8.7%) is higher in our study when compared to other studies. An Earlier study[7] done in our institute revealed a SSI rate of 8% in Inguinal hernias. There is no reliable data regarding the wound infection rates in the hospitals in the developing world and given the fact that few trials[4,9] even in the developed world have reported 8 to 9% SSI rates, our trial may reflect the reality about SSI in developing countries.

Table 4
Correlation between patient parameters and surgical site infection.

	Infected group	Uninfected group	*p* Value
Age[a]	48.00 ± 16.32	44.70 ± 15.95	0.289
Sex[b]			
Male	29	301	1.000
Female	0	4	
ASA grade[b]			
ASA I	26 (89.7%)	282 (92.5%)	0.591
ASA II	3 (10.3%)	23 (7.5%)	
Co morbidity[b]			
Present	3 (10.3%)	32 (10.3%)	0.980
Absent	26 (89.7%)	273 (89.5%)	
Type of hernia[b]			
Unilateral	26 (89.7%)	281 (92.1%)	0.912
Bilateral	3 (10.3%)	24 (7.9%)	

Table 5
Correlation between operative variables and surgical site infection.

	Infected group	Uninfected group	*p* Value
Preoperative stay (in days)[a]	5.31 ± 3.16	4.06 ± 3.03	0.035
Anesthesia[b]			
SA	24 (82.8%)	271 (88.9%)	0.315
GA	1 (3.4%)	11 (3.6%)	
LA	4 (13.8%)	22 (7.2%)	
EPIDURAL	0	1 (0.3%)	
Grade of surgeon[b]			
Consultant	4 (13.8%)	34 (11.1%)	0.669
Resident	25 (86.2%)	271 (88.9%)	
Duration of surgery (in minutes)	58.45 ± 17.45	52.52 ± 15.28	0.05

[a] Values expressed in mean ± standard deviation.
[b] Values expressed in numbers and percentage.

A few studies have shown that grade of the surgeon may be a significant risk factor for SSI.[12] Majority of the procedures were performed by residents in our study ($n = 296$), as ours is a teaching institute. The grade of the surgeon was not a statistically significant risk factor for SSI in our study. Taylor et al.[13] in their study concluded that the grade of the surgeon does not influence the rate of SSI in groin hernia repair. Aufenacker et al.[8] also reported similar results from their study.

In our study, there is a positive correlation between the duration of pre-operative hospital stay and the development of post operative SSI. The mean pre-operative hospital stay was 5.31 ± 3.16 days in the patients with SSI in comparison to 4.06 ± 3.03 days in patients without SSI. The difference was statistically significant ($p = 0.035$). It is a well known fact that increased preoperative hospital stay increased the risk of colonization with resistant bacteria.[14] Since we do not have day care facility; all our patients were operated as in patients, which is the reason for increased preoperative hospital stay in our study. We believe that this will be the case in majority of institutes in the developing world.

Only 2 (7%) out of 29 patients developed wound infection during their hospital stay, whereas the vast majority (94%) were diagnosed during followup, most often during their first scheduled visit, in the 2nd post operative week. In the study done by Perez et al.[10] on the role of antibiotic prophylaxis in mesh repair, all the infections were diagnosed after hospital discharge. This again emphasizes the need for followup to establish the true incidence of SSI.

Vast majority of SSI occurring after hernia repair are superficial surgical site infection and are treated by simple drainage with or without antibiotics.[6] 93% of the SSI in our study was superficial SSI. All the SSIs reported in the studies done by Celdran et al.[9] and Tzovaras et al.[11] were superficial SSI. The incidence of mesh

The most common organism isolated was *Staphylococcus aureus* (Table 7), which forms a part of normal skin flora. Staphylococcus is the most common isolate in surgical site infection following hernia repair in various studies.[4,7,10,11] *Staph. aureus* was the organism isolated in 12 patients (70.5%) with culture positive infection. More than one organism was isolated in 2 patients (11.7%) with culture positive infection.

Table 6
Correlation between hospital stay and surgical site infection.

	Infected group	Uninfected group	*p* Value
Post operative stay[a]	3.38 ± 3.86	2.5 ± 1.3	0.070
Total hospital stay[a]	9.69 ± 4.37	7.53 ± 3.10	0.001

[a] Values expressed in mean ± standard deviation (in days).

Table 7
Microorganisms in culture positive wound infections.

Micro organism	Number (percentage)
Staphylococcus aureus	12 (70.5%)
Streptococci	2 (11.7%)
Klebsiella pneumoniae	2 (11.7%)
E. coli	1 (5.8%)
Enterobacteria	1 (5.8%)
Multiple organisms	2 (11.7%)

infection reported in literature varies from 0.35% to 1%.[4,8,15] The incidence of deep SSI was 0.6% in our study. Aufenacker et al.[8] reported an incidence of 0.3% for deep SSI in their study within a followup period of 3 months. One patient had mesh removal due to SSI in our study.

Cefazolin was the antibiotic used in our study. It was chosen because of its proven efficacy against the common organisms like *Staphylococcus aureus*, longer duration of action and low cost.[16] Since majority of SSI in our study were due to *Staph. aureus*, the question of failure of prophylaxis due to inefficient antibiotic is ruled out. Cefazolin was the antibiotic used in studies done by Celdran et al., Morales et al., and Perez et al.[9,17,10] One gram of Cefazolin was given intravenously at the time of induction of anesthesia. This is consistent with the studies done by other authors.

The economic impact of SSI was not assessed in our study. However since 93% of infections were Superficial SSIs, we believe the cost effectiveness of antibiotic prophylaxis in the absence of conclusive benefit is questionable.

The incidence of wound infection was 9% in the control group and 1% in the antibiotic group in the study done by Yerdel et al.[4] The authors showed a significant difference in wound infection between the antibiotic and control groups. Celdran et al.[9] reported SSI rates of 8% and 0% in the control and antibiotic group respectively and had similar conclusions.

Aufenacker et al.[8] showed that the incidence of SSI was 1.8% in the control group and 1.6% in the antibiotic group. The author concluded that prophylactic antibiotics did not prevent SSI in open mesh repair of inguinal hernias. The SSI rates reported by Perez et al.[10] were 3.3% and 1.7% in the control and antibiotic group respectively and the author did not find any benefit with prophylactic antibiotics. A similar conclusion was drawn by Tzovaras et al.,[11] where the incidence of SSI in control and antibiotic groups were 4.7% and 2.6% respectively. It should be noted that studies in which the rates of SSI are higher have reported that prophylactic antibiotics are beneficial, whereas similar conclusion could not be derived in the studies with low rates of SSI.

To conclude, in our study, even though the rates of SSI were high in both the antibiotic and control groups, the difference was not statistically significant. Based on our results we conclude that prophylactic antibiotics do not decrease the rate of SSI in mesh repair of inguinal hernias and hence routine use of prophylactic antibiotics cannot be recommended for the same.

Conflict of interest

None.

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Ethical approval

The study was approved by the institute ethics committee. Reference Number – No. Edn.6(10)/2007.

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